UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/559,502	05/12/2006	D. Gary Gilliland	4-33222A	8715

1095 7590 04/28/2008

NOVARTIS
CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 104/3
EAST HANOVER, NJ 07936-1080

EXAMINER	
SZNAIDMAN, MARCOS L	
ART UNIT	**PAPER NUMBER**
1611	

MAIL DATE	DELIVERY MODE
04/28/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/559,502	GILLILAND ET AL.	
	Examiner	Art Unit	
	MARCOS SZNAIDMAN	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 January 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *22-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This office action is in response to applicant's reply filed on January 31, 2008.

Election/Restrictions

Applicant's election of compound of formula VII (PKC412 or Midoustarin), as the elected species, in the reply filed on January 31, 2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Status of Claims

Cancellation of claims 1-21, and addition of claims 22-38 is acknowledged

Claims 22-38 are currently pending and are the subject of this office action.

Claims 22-38 are presently under examination.

Priority

The present application is a 371 of PCT/EP04/06070 filed on 06/04/2004, and claims priority to provisional application No. 60/476,376 filed on 06/06/2003.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 22-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cools et. al. (Cancer Cell (May 2003) 3:459-469).

Claims 22, 26, 30 and 33 recite a method of treating a FIP1L1-PDGFRalpha-induced myeloproliferative disease, which comprises administering to a mammal subject in need of treatment a specified dose of PKC412.

For claims 22, 26, 30 and 33, Cools et. al. teach a method of treating of FIP1L1-PDGFRalpha-induced myeloproliferative disease with PKC412 (see for example abstract). They also teach the following dosage of PKC412 (see page 468, first paragraph): 100 mg/kg/day per animal every 24 hs by oral gavage. Cools et. al do not teach the dosage disclosed in claims 22, 26, 30 or 33. However, it's within the capability of the ordinary artisan to determine these amounts for a particular patient and adjust dosage amounts based on the observed clinical effectiveness.

Claim 34 recites the same limitations as claim 33, wherein the FIP1L1-PDGFRalpha-induced myeloproliferative disease is hypereosinophilic syndrome.

For claim 34, Cools et. al. teach that one of the myeloproliferative diseases treated with PKC412 is hypereosinophilic syndrome (see for example abstract).

Claim 35 recites the same limitations as claim 34, wherein the hypereosinophilic syndrome is resistant to imatinib.

For claim 35, Cools et. al. teach that hypereosinophilic syndrome that is resistant to imatinib, can be treated with PKC412 (see for example abstract).

Claim 36 recites the same limitations of claim 35, wherein the PDGFRalpha has a T674I mutation.

For claim 36, Cools et. al. teach that PKC412 is effective in the treatment of T674I mutated FIP1L1-PDGFRalpha-induced disease (see abstract).

Claims 37 and 38, recite the same limitations as claim 35, wherein a specific dosage of PKC412 is administered. For claims 37 and 38, Cools et. al. teach the following dosage of PKC412 (see page 468, first paragraph): 100 mg/kg/day per animal every 24 hs by oral gavage. Cools et. al. do not teach the dosage disclosed in claims 37 and 38. However, it's within the capability of the ordinary artisan to determine these amounts for a particular patient and adjust dosage amounts based on the observed clinical effectiveness.

Claims 23 and 27 recite a method of treating hypereosinophilic syndrome, which comprises administering to a mammal subject in need of treatment a specified dose of PKC412.

For claims 23 and 27, Cools et. al. teach a method of treating hypereosinophilic syndrome with PKC412 (see for example abstract). They also teach the following dosage of PKC412 (see page 468, first paragraph): 100 mg/kg/day per animal every 24 hs by oral gavage. Cools et. al do not teach the dosage disclosed in claims 23 or 27. However, it's within the capability of the ordinary artisan to determine these amounts for

a particular patient and adjust dosage amounts based on the observed clinical effectiveness.

Claims 24 and 28 recite the same limitations as claim 23, wherein the hypereosinophilic syndrome is resistant to imatinib.

For claims 24 and 28, Cools et. al. teach that hypereosinophilic syndrome that is resistant to imatinib, can be treated with PKC412 (see for example abstract).

Claims 25 and 29 recite the same limitations of claim 24, wherein the PDGFRalpha has a T674I mutation.

For claims 25 and 29, Cools et. al. teach that PKC412 is effective in the treatment of T674I mutated FIP1L1-PDGFRalpha-induced disease (see abstract).

At the time of the invention, it would have been *prima facie* obvious for a person of ordinary skill in the art to combine the teachings of Cools et. al. (treating myeloproliferative diseases (hypereosinophilic syndrome in particular) with or without imatinib resistance as a consequence of T674I mutation), and adjust the dosage as needed, with the motivation of achieving a better treatment of myeloproliferative diseases (hypereosinophilic syndrome in particular), thus resulting in the practice of claims 22-38 with a reasonable expectation of success.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARCOS SZNAIDMAN whose telephone number is (571)270-3498. The examiner can normally be reached on Monday through Thursday 8 AM to 6 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward can be reached on 571 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MLS
April 10, 2008

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615